

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. : 10/679,763
Filed : October 6, 2003
Applicant : Barry M. Yomtov, et al.
Title : Medical Device for Neural Stimulation and
Controlled Drug Delivery

TC/AU : 3762
Examiner : Terri L. Smith

Docket No. : 17509-0072
Customer No. : 29052

SECOND DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, John T. Santini Jr., hereby declare that:

1. I am the President and Chief Executive Officer of MicroCHIPS, Inc., which is the assignee of the above-identified patent application. My employment compensation from MicroCHIPS Inc. includes cash, stock, and stock options in the company. I have a Ph.D. in chemical engineering from Massachusetts Institute of Technology and over 13 years of experience in the development of micro-reservoir based devices for the protection and selective exposure or release of chemicals, such as pharmaceuticals, diagnostic reagents, or enzymes on biosensors. I am an inventor on 20 issued U.S. patents directed to this technology.

2. I have read the Office Action mailed March 27, 2007, in connection with the present patent application. I also have again read U.S. Patent Publication No. 2002/0111601 by Thompson (hereinafter "Thompson") upon which the Examiner relies to reject claims 1-3, 5-7,

12-17, 20-28 and 31-36. The rejections are based upon a factually inaccurate reading of Thompson.

3. The Office Action errs in the assertion that “the structure of Thompson shows the claimed reservoir cap structure and means for electrothermal ablation at Fig. 6, elements 270 and 272, paragraph [0066] lines 8-10 and paragraphs [0068]-[0072].” (P.3, ¶3) Neither these particular parts of Thompson nor any others of it disclose or suggest a reservoir cap connected to two conducting leads nor any other means for electrothermal ablation, as detailed in my first Declaration under 37 C.F.R. § 1.132 (“the First Declaration”) and as will be further clarified herein.

4. The First Declaration admittedly contained a minor typographical error: My prior statement that “Thompson teaches that cathode conductor 286 is not connected to the cap 270” used an incorrect reference character. Rather, what I intended to say was that cathode conductor 284 is not connected to the cap 270. Similarly, cathode conductor 286 is not connected to the cap 272. It is abundantly clear from FIGS. 6 and 7 that reservoir cap 270 or 272 is connected *only to single lead* 280 or 282, respectively.

5. Moreover, Paragraph [0069] of Thompson is not contradictory. One skilled in the art reading the sentence “[e]ach of these additional cathode conductors, shown in cross-section as conductors 284 and 286, are located adjacent to, but electrically and mechanically isolated from, a respective reservoir” would understand “reservoir” in this instance to refer to the reservoir cap member 270 or 272, and not to the underlying reservoir 260 or 262, because that is what matters to the anode/cathode functionality, because that is what is illustrated in FIGS. 6 and 7, and

because it is clear from Paragraph [0073] that that is what applicant intended in Paragraph [0069]. Paragraph [0072] says “FIG. 7 is a top plan view of tip portion 118 of catheter assembly 102 illustrating reservoir cap 270 and the associated conductors....This view shows the manner in which wire 284, which serves as the cathode conductor, is adjacent to, but electrically isolated from, reservoir 270.” (emphasis added). Accordingly, it is an evident typographical error in Thompson where reservoir cap 270 is referred to as “reservoir 270.”

6. Paragraph [0073] of Thompson further discloses that “[w]ire 280 is mechanically and electrically coupled to reservoir [cap] 270 in the manner discussed above.” Here, again, Thompson refers to the “reservoir cap member” as simply a “reservoir.” I note that it would be inaccurate to interpret the term “reservoir” here to refer to reservoir 260 because wire 280 clearly is not mechanically connected to reservoir 260. See Fig. 6. By corollary, the Examiner’s interpretation of “reservoir” in Paragraph [0069] necessarily is inaccurate. For all of these reasons, one skilled in the art reading Thompson *as a whole* therefore understands Paragraph [0069]’s description of “reservoir” to mean the reservoir cap member 270 or 272.

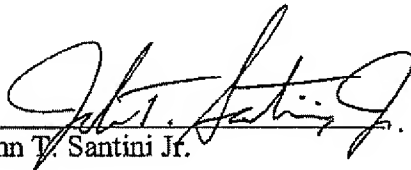
7. Applicants’ claims require means for disintegrating a reservoir cap by electrothermal ablation. An electrothermal ablation means requires a structure that provides **internal heating of the reservoir cap by the reservoir cap to cause the reservoir cap *itself* to disintegrate**. Thompson does not teach electrothermal ablation. First, electrothermal ablation requires that the reservoir cap be operably connected to both an electrical input lead and an electrical output lead, so that electrical current may be applied through the reservoir cap via the

pair of connected conducting leads. In contrast and as detailed in the First Declaration, Thompson fails to disclose a structure of a reservoir cap connected to a pair of conducting leads.

8. Second, electrothermal ablation requires *resistive heating* effective to disintegrate the reservoir cap. In contrast, Thompson discloses no mechanism or structure for resistive heating of the reservoir cap member. Thompson discloses only an *electrochemical* mechanism for causing a cap member to be disintegrated. The electrochemical mechanism does not involve resistive heating in an amount effective to disintegrate the reservoir cap member. The Office Action fails to provide any sound technical explanation for a contrary reading of Thompson.

9. I declare that all statements made herein of my own knowledge and belief are true and that all statements made on information and belief are believed to be true, and further that the statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

September 26, 2007


John T. Santini Jr.